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(Attorney for Applicant)

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**FEB 25 2000**

In re Application of :  
Ted Christopher :  
Application No. 08/746,360 :  
Filed: November 8, 1996 :  
For: FINITE AMPLITUDE :  
DISTORTION-BASED :  
INHOMOGENEOUS PULSE ECHO :  
ULTRASONIC IMAGING :

**SPECIAL PROGRAMS OFFICE  
DAC FOR PATENTS**

DECISION GRANTING PETITION  
TO INSTITUTE PUBLIC USE PROCEEDINGS

On March 20, 1998, a petition to institute public use proceedings against the claims of the above-identified application has been considered in connection with two Examiner's reports dated November 6, 1998 and November 19, 1999, respectively. The Examiner's first report was previously sent as an attachment to the Notice mailed June 30, 1999. However, since this is an ex parte case, no copy of the Examiner's first report was sent to the petitioner. The Notice mailed June 30, 1999, set September 9, 1999, as the date for the preliminary hearing to determine whether a public use proceeding should be instituted.

On September 2, 1999, a petition was filed requesting that the Examiner reconsider the determination that a prima facie case had been made of the prior public use of the invention claimed in the application.

On September 9, 1999, the preliminary hearing was held.

In response, on September 14, 1999, a summary of the arguments presented at the preliminary hearing was submitted by applicant's attorney. Applicant argued, in part, that the Examiner should reconsider the determination that a prima facie case had been made of the prior public use of the invention claimed in the application.

In response, on September 20, 1999, a summary of the arguments presented at the preliminary hearing were submitted by petitioner's attorney. Petitioner argued, in part, that the present public use proceeding should be granted without reconsideration of the Examiner's findings.

As requested, the application was again forwarded to the Examiner for a second report including a reconsideration of his determination that a prima facie showing had been made. On reconsideration, the Examiner again determined that a prima facie showing had been made. Since this is an ex parte case, no copy of the Examiner's second report has been sent to petitioner.

In view of the above, the petition under 37 CFR 1.182, or in the alternative under 37 CFR 1.183 filed September 2, 1999, requesting that the Examiner reconsider his determination that a prima facie case had been made of the prior public use of the invention claimed in the application is dismissed as moot.

It appears that the showing made in the petition to institute public use proceedings filed March 20, 1998, is sufficient to justify the institution of a public use proceeding. The application is accordingly referred to the Examiner of Technology Center Art Unit 3737 who will set a schedule of times for taking testimony and conduct the proceeding. See MPEP 720.04 and 720.05. Other proceedings in connection with this application are otherwise suspended.

The petition to institute public use proceedings is granted.

Petitioners' copy of this "Decision" has been edited to delete the application number, filing date, name of applicant and the title of the invention.



Charles Pearson  
Patent Legal Administrator  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

fas

Enclosure: Copy of Examiner's second report



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**FEB 25 2000**

**SPECIAL PROGRAMS OFFICE  
DAC FOR PATENTS**

In re Application of :  
[ ] :  
Application No. [ ] : DECISION GRANTING PETITION  
Filed: [ ] : TO INSTITUTE PUBLIC USE PROCEEDINGS  
For: [ ] :

On March 20, 1998, a petition to institute public use proceedings against the claims of an application identified by petitioner as application No. 08/746,360 has been considered in connection with two Examiner's reports. The Examiner's first report was previously sent to the applicants. However, since this is an ex parte case, no copy of the Examiner's first report was sent to the petitioner. The Notice mailed June 30, 1999, set September 9, 1999, as the date for the preliminary hearing to determine whether a public use proceeding should be instituted.

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(Attorney for Applicant)

In re Application of :  
Ted Christopher : **MEMORANDUM RE PETITION**  
Serial No. 08/746,360 : **UNDER 37 C.F.R. 1.182 OR 1.183**  
Filed: November 8, 1996 : **TO RECONSIDER DECISION TO**  
For: Finite Amplitude Distortion- : **INSTITUTE PUBLIC USE PROCEEDING**  
Based Inhomogenous Pulse-Echo :  
Ultrasonic Imaging :

#### Reconsideration Decision Summary

The Petition under 37 C.F.R. 1.182 or, in the alternative under 37 C.F.R. 1.183 filed September 2, 1999 for the Examiner to reconsider the decision of November 6, 1998 that a prima facie case has been made of prior public use of the invention claimed in the application by the Petition For Public Use Proceedings filed March 20, 1998 is *denied*.

#### Reconsideration Decision Reasoning

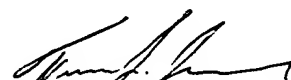
The Petition argues that insofar as both independent method claim 2 and independent apparatus claim 13 respectively recite the step of and means for forming an image *principally* from one of the received higher order components of the reflected signal which has undergone finite amplitude distortion along the propagation path within the investigated tissue, the two public use circumstances alleged by the Public Use Petition Under 37 C.F.R. 1.292 which are stated to involve initial or baseline production of a discernible tissue harmonic image prior to injection of a harmonic-inducing contrast agent using a modified ultrasound scan imaging system adapted for harmonic contrast agent vascular scanning cannot suffice to support a prior public use finding for the invention since it does not inherently follow that these uses formed an image principally from the second harmonic but merely a measurable image therefrom and motivation is lacking to supplement the disclosure shortfall.

It may be recalled that the term *principally* was introduced into the base claims in the Amendment under 37 C.F.R. 1.116 filed June 18, 1998 to distinguish over harmonics generated at the scatterer such as contrast agent or endogenous vascular microbubbles. This term does not per se appear in the original specification or claims but was allowed entry as inherently pertaining in its context to a device such as applicant's which is designed and adapted to produce an harmonic image based on tissue non-linear distortion effects as opposed to other phenomena. Such a catchment does not disallow the relevance of the usages described by the Public Use Petition merely because that Petition's affidavits (for example the Chandler, Holley and Main affidavits) refer to visualization of tissue harmonics in the baseline image as having been 'seen' or 'present in at least a measurable part', since in the absence of a contrast agent injectate only the non-linearities of tissue as opposed to those of the transmit pulse or system would be spatially organized as to provide an image, begging the question as to what is principally visualized in the residuum when the contrast agent is not yet provided.

Additionally, an instance of identified public use under 35 USC 102(b) serves to define prior art

insofar as that which was in public use more than a year prior to the inventor's filing date becomes prior art for purposes of obviousness combination. The Examiner's understanding is that here, in this reconsideration decision context, he is not charged per se with combining art however insofar as the Reconsideration Petition argues against combinability of additional art in the manner of a rebuttal to an art rejection, the general response is made that when applicant's disclosure is reviewed to determine what principal technical features allow the Figure 1 system to be specially adapted to image tissue harmonics, the specification pages 6-8 indicates that the theoretical focussing or resolution-increasing advantages of tissue harmonic imaging can be achieved by adapting an ultrasound imaging system such that either (a) the returned signal is high-pass filtered to enhance its harmonic strength and remove the fundamental, or (b) the transmitted signal is stepped up in amplitude in a two-pulse scheme wherein the lower level signal is then subtracted to unmask the non-linear or harmonic effect from the linear reflection effect. Both techniques were heretofore known in relation to microbubble harmonic imaging, for example in the case of the former see **Williams** (WO 91/15999 made of record in Office action paper No. 11 mailed March 19, 1998) page 12 discussion of filtering within the signal processing unit; in the case of the latter see **Brock-Fisher** (US5577505, of record with the Supplemental IDS paper No. 8 filed September 25, 1997), col. 2 discussion of the two-pulse subtraction method and col. 2 line 50-60 note that the method yields both the microbubble contrast agent and tissue harmonics with differences in scale thereof. Hence a proper motivation exists to modify the Accuson system as used publicly by signal processor filtering and/or by two-pulse subtraction to enhance its structure and method of use for improving its harmonic sensitivity whereupon a question exists as to whether the public use disclosure of obtainance of a measurable tissue harmonic image renders the invention obvious in terms of refinements which might be practiced by those of ordinary skill so as to produce a 'large' or 'principally' tissue harmonic image versus a 'measurable' or 'observable' harmonic image in a baseline protocol where a contrast agent is not yet added.

Accordingly, the disclosed public use by the 37 C.F.R. 1.292 Petition is deemed sufficient to establish a prima facie case of public use of the claimed invention and the Reconsideration Petition is *denied*.

  
**Francis J. Jaworski**  
Primary Examiner

FJJ:fjj  
11-19-99